



# Office Action Summary

Application No.  
**09/766,778**

Applicant(s)  
**Papathanassiu**

Examiner  
**Michael Borin**

Art Unit  
**1631**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 23, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) 1-10, 18, and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-17 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language priority document has been received.

2 ☒ Notice of Draftsperson's Patent Drawing Review (PIO 946)

5 ☐ Notice of Informal Patent Application (PIO 152)

3 ☒ Information Disclosure Statement (PIO 1449 Paper No. 3,7

6 ☐ Other

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## **DETAILED ACTION**

### ***Status of Claims***

1. Response to restriction requirement filed 07/23/02 is acknowledged. Applicant elected, with traverse, Group II, claims 11-20. Insofar as applicants have not specifically pointed out the reasons supporting the statement of the traversal, applicants' election is taken to be without traverse. See MPEP 818.03(a). The requirement is still deemed proper and is therefore made FINAL. Claims 1-10 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. It is further noted that claim 20 was erroneously indicated as a part of Group II, as this claim depends on claim 10, and thus belongs to Group I. Therefore, claim 20 is withdrawn from further consideration for the reasons set forth for claims 1-10. Cancellation of claims 1-10, 20 is requested.

In regard to election of species, applicant elected SEQ ID No. 1. Claims reading on the elected species are claims 11-17,19. Claim 18 is withdrawn from consideration as reading on non-elected species.

### ***Priority***

2. The claim for priority under 35 U.S.C. 120 is objected to because it is not the

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***Claim Rejections - 35 USC § 112, first paragraph.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 12-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "active" fragments comprising Kunitz-3 domain, does not reasonably provide enablement for any randomly taken fragments of TFPI.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to compositions of proteins comprising TFPI fragments having antiproliferative activity. Specification clearly states that Kunitz-3 domain is required for a fragment to possess the required activity. See Example 5, and page 11, lines 25-27. There is no other examples or guidance disclosing any other "active" fragments.

***Claim Rejections - 35 USC § 102 and 103***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 11-17,19 are rejected under 35 U.S.C. 102(a) as being anticipated by Steinhubl et al (J.Amer.College of Cardiology 29 (2), 243A, 1997; the reference became available in George Washington University's Himmelfarb Library on 01/30/97) or Khouri et al (Surgical Forum 46, 389-391, 1995) or Markland et al. (US Patent 5,795,865).

Steinhubl teaches compositions of TFPI (i.e. protein of instant SEQ ID No. 1) and demonstrates that TFPI inhibits neointimal proliferation. Steinhubl teaches that TFPI is administered in solutions (i.e., in as a composition comprising excipient) either as an infusion or locally.

Similarly, Khouri teaches that administration of compositions comprising TFPI inhibits intimal hyperplasia induced by arterial interventions. See p. 390, conclusions.

The TFPI compositions of Steinhubl or Khouri read on TFPI compositions as claimed. In regard to fragments, TFPI contains "comprises" fragments as claimed,

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5. Claims 11-17,19 are rejected under 35 U.S.C. 102(a) as being anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over Markland et al. (US Patent 5,795,865).

Markland et al. teach inhibitors of kallikrein and compositions thereof. In particular, peptide of SEQ ID 35 in Markland is a preferred inhibitor of kallikrein. See col. 19-20, Table 2 and col. 4, lines 21, 26 (human LACI-K3). The referenced peptide of SEQ ID 35 is a fragment of Kunitz-3 domain of lipoprotein-associated coagulation inhibitor, and it comprises, at positions 30-51, a fragment of TFPI.

The referenced compositions read on compositions comprising TFPI fragments, fragments of Kunitz-3 domain in particular.

The Markland reference teaches the peptide that meets the structural limitation claimed. Although the reference does not teach the functional limitation of the peptide, such a limitation would be inherent in the peptide since it meets the structural limitations of the claim. A reference which is silent about a claimed invention's feature is inherently anticipatory if the missing feature is necessarily present in that which is described in the reference.

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A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure and composition, the properties applicant discloses and/or claims are necessarily present. In re Spada , 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Where the claimed and prior art products are identical or substantially identical in composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977).

it has been held that where applicant claims a composition in terms of function, property or characteristic where said function is not explicitly shown by the reference and where the examiner has explained why the function, property or characteristic is considered inherent in the prior art, it is appropriate for the examiner to make a rejection under both the applicable section of 35 USC 102 and 35 USC 103 such that the burden is placed upon the applicant to provide clear evidence that the respective compositions do in fact differ.

***Conclusion.***

6. No claims are allowed

7. Any inquiry concerning this communication or earlier communications from the

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305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

October 7, 2002

mlb



## Attachment for PTO-948 (Rev. 03/01, or earlier)

6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

#### 1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

#### 2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

#### Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).